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ARTYKUŁ ORYGINALNY / *ORIGINAL ARTICLE*

Access for percutaneous coronary intervention in ST segment elevation myocardial infarction: radial vs. femoral — a prospective, randomised clinical trial (OCEAN RACE)

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Abstract

Background: Percutaneous treatment of patients with ST segment elevation myocardial infarction (STEMI) has become the standard and default mode of management as recommended by the European Society of Cardiology guidelines for managing acute myocardial infarction in patients presenting with STEMI. The choice of vascular access is made by the operator and has a potential impact on the safety and efficacy of the procedure and outcomes.

Aim: To understand the influence of a radial approach on bleeding complications and angiographic success, we performed a prospective, controlled randomised trial.

Methods: Patients were allocated to radial (TR) or femoral (TF) vascular access. The primary endpoints were major bleeding by the REPLACE-2 scale and minor bleeding by the EASY scale (TR arm) or the FEMORAL scale (TF arm). Other outcomes included procedural data, in-hospital and long-term survival.

Results: There were 103 patients analysed in total, 52 in the TR arm and 51 in the TF arm. The demographic and clinical baseline characteristics were well matched between the two study groups. The frequency of the primary endpoint was the same in both arms (TR: 25.0% vs. TF: 33.3%, $p = 0.238$). In per protocol analysis, there was a significant benefit of the TR approach among independent operators (17.4% vs. 36.8%, $p = 0.038$). Major bleeding by the REPLACE-2 scale occurred in 4.2% of patients (TR: 5.8% vs. TF: 3.9%, $p = 0.509$). There were no differences in terms of the rate of major cardiac adverse events, which happened in 10.7% of the study population (TR: 9.6% vs. TF: 11.8%, $p = 0.48$). In the TF arm, there was a trend towards a higher risk of local bleedings (TR: 22.4% vs. TF: 37.7%, $p = 0.081$) and a significantly higher frequency of local haematoma (class III, EASY/FEMORAL) (TR: 0% vs. TF: 9.8%, $p = 0.027$).

Conclusions: There were no significant differences between the TR and TF approaches in terms of clinical efficacy and patient safety. However, patients treated by independent operators might benefit from TR access. The overall complication risk of percutaneous coronary intervention treatment of STEMI patients remains low.

Key words: STEMI, radial, femoral, vascular access, bleeding

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INTRODUCTION

Percutaneous treatment of patients with ST segment elevation myocardial infarction (STEMI) has become the standard mode of care. It is recommended by the European Society of Cardiology guidelines for the management of acute myocardial infarction in patients presenting with STEMI [1]. STEMI patients have a high mortality risk compared to the acute coronary syndrome (ACS) population [2]. In order to prevent major ischaemic injury of the myocardium, this life-saving procedure should be performed promptly, using pre-treatment with

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potent antiplatelet and antithrombotic agents and mechanical devices such as thrombectomy. Experienced operators should consider a radial approach (class of recommendation: IIb, level of evidence: B). To build up the body of evidence supporting this recommendation with an aim of lifting it to class I, we present the results of an access f**o**r per**c**utan**e**ous coron**a**ry intervenţio**n** in STEMI: **ra**dial vs. femoral — prospe**c**tiv**e**, randomised clinical trial (OCEAN RACE). The study was begun in 2010 before any recommendations were available and was designed as a multidimensional assessment including clinical safety and efficacy, as well as health-related quality of life and cost-effectiveness. Here, we report the main safety and efficacy clinical results of the analysis.

METHODS

OCEAN RACE was a randomised, open-label, controlled, single-centre clinical trial that compared the risk of major and minor bleedings in patients with STEMI treated with percutaneous coronary intervention (PCI) in a high volume invasive cardiology centre. This was an investigator-initiated trial funded by the authors and approved by the local ethics committee. Between September 2010 and October 2012, we screened patients, looking for those fulfilling the inclusion and exclusion criteria as reported before (Table 1) [3]. After informed consent was acquired, patients were randomised to femoral or radial access. The random sequence was generated and the allocation was concealed using opaque envelopes containing icon-cards. The operator was allowed to change the treatment arm based on clinical scenario and safety issues.

Table 1. Inclusion and exclusion criteria

Inclusion criteria
Pain duration between 20 min and 24 h
ST segment elevation measured at the J point in two contiguous leads ≥ 0.25 mV in men below the age of 40 years, ≥ 0.2 mV in men over the age of 40 years, or ≥ 0.15 mV in women in leads V_2–V_3 and/or ≥ 0.1 mV in other leads (in the absence of left ventricular hypertrophy or LBBB) or newly emerged LBBB
Age ≥ 18 years
Patient's informed consent
Exclusion criteria
International normal ratio > 1.4
Thrombocytopenia < 100×10^3
Previous coronary artery bypass grafting
Known vascular access difficulties or complications
Active bleeding
Gastric or duodenal peptic ulcer
Current or planned dialysis
Severe liver failure (MELD > 10 points)
Uncontrolled hypertension (> 160/100 mm Hg)
Cardiogenic shock
Low compliance to long-term follow-up

LBBB — left bundle branch block; MELD — Model of End-Stage Liver Disease

End-points

The primary end-point was a composite of major bleeding according to the definition published in the Randomised Evaluation in Percutaneous Coronary Intervention Linking Angiomax to Reduced Clinical Events 2 (REPLACE-2) study, and minor bleedings defined by the EASY scale (radial arm — TR) and FEMORAL scale (femoral access — TF) [3–5]. Secondary end-points included: 1) angiographic success defined by the Thrombolysis in Myocardial Infarction (TIMI) flow classification as TIMI 3 and residual stenosis below 20%; 2) clinical efficacy defined as survival and no major adverse cardiac event (MACE) during in-hospital stay; and 3) long-term mortality.

Study flow

Patients were transported directly to a catheterisation room; an electrocardiogram teletransmission was used to facilitate the diagnostic process. Patients received standard pharmacotherapy for ACS including dual antiplatelet therapy (300 mg of aspirin, 600 mg of clopidogrel) and antithrombotic therapy (unfractionated heparin 70–100 IU/kg). The use of IIb/IIIa inhibitors was left to the operator's discretion. The default catheter size was 6 F for a radial and 6 F/7 F for a femoral approach. We recorded baseline clinical characteristics of the patient, time-delays, procedural data and clinical events during the hospital stay. Procedures were performed by independent radial operators who carry out at least 200 PCIs per year using a radial approach, and operators who were in training (< 200 PCI per year). All in-hospital safety incidents were recorded. After discharge, patients were followed for 12 months to assess the mortality risk.

Predefined subgroups analysis

There were six predefined study subgroups that were analysed separately in the scope of the primary-end point. These included: age above 65 years, women, body mass index ≥ 25, operator experience (independent operator), usage of IIb/IIIa inhibitor and renal insufficiency.

Statistical analysis

The comparative analysis of features within TR vs. TF group was performed using Student's t-test, the Kruskal-Wallis test, χ^2 test and Fisher's exact probability test as required. Results are presented and mean values or hazard ratio (HR) with 95% confidence interval (95% CI). Meta-analysis was performed as per the recommendations of the Cochrane Collaboration and the MOOSE statement [6]. I^2 statistic was calculated to estimate heterogeneity among studies. Since significant heterogeneity was present, random-effects models were used to

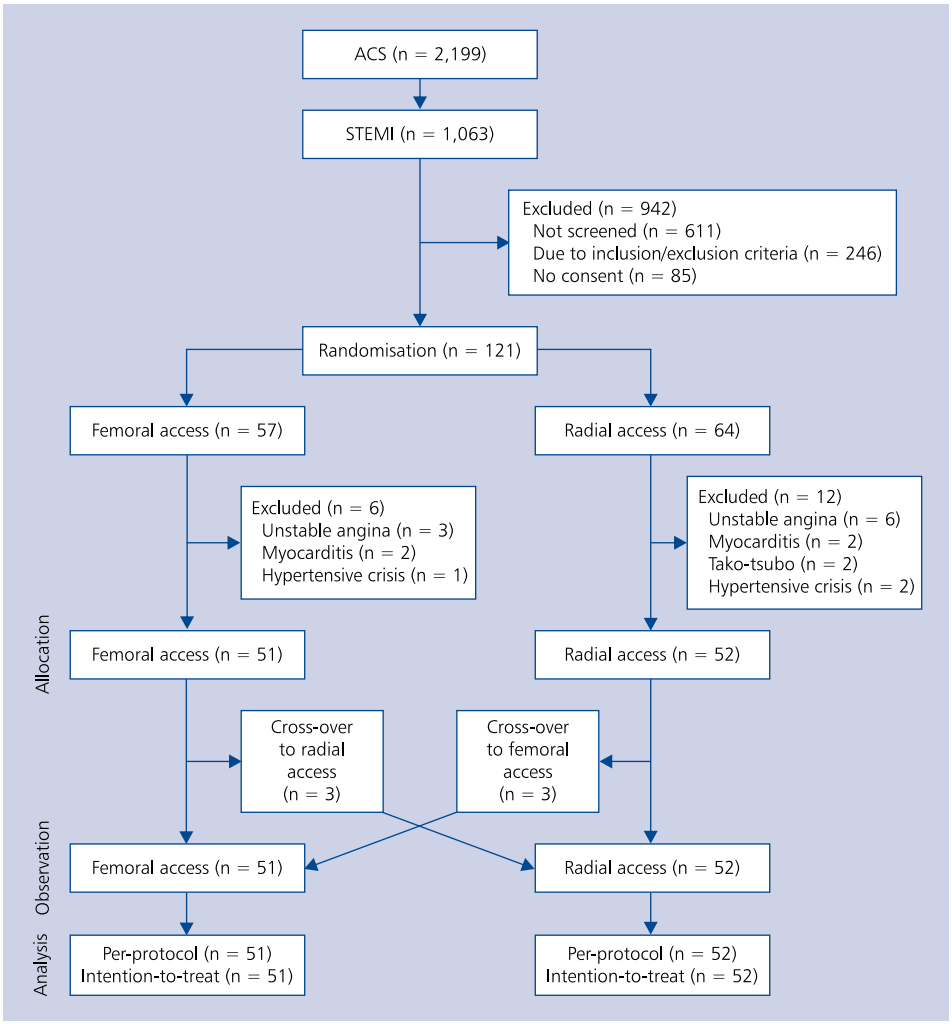

Figure 1. Study-flow chart; ACS — acute coronary syndrome; STEMI — ST segment elevation myocardial infarction

compute odd ratios with 95% CI. P-values of less than 0.05 are considered as statistically significant.

RESULTS

Of the 1,063 STEMI patients hospitalised during the screening period at the 1st Department of Cardiology of the Medical University of Warsaw, Poland, 452 were screened for the study and 121 signed informed consent and were eventually included in the trial. Patients were randomised to a transfemoral approach (TF, n = 57) or a transradial approach (TR, n = 64). After randomisation, 18 patients were excluded and six were crossed-over to the other approach (Fig. 1). There were no significant differences regarding the clinical characteristics between the study groups at baseline (Table 2).

Procedure

All patients underwent angiography, 101 (98.1%) from right radial or femoral artery. The pulse on radial artery was classified as good (70.9%), acceptable (25.2%) or weak (3.9%). The need for crossover of the vascular access occurred in 8.7% and did not differ between subgroups (TR: 9.6% vs. TF: 7.8%, p = 0.512). Most culprit lesions caused total vessel occlusion (TIMI 0, 62.6%) and were localised in the left anterior descending artery (LAD) or right coronary artery (RCA): 46.1% and 39.2%, respectively. Mechanical thrombectomy was used in 56.4% and 62.8% of patients who received IIb/IIIa inhibitor. Stent was implanted in 88.1% of cases. Direct stenting technique was more frequently used in TR arm (13.2% vs. 2.0%, p = 0.038). Drug eluting stent was implanted in 12.6% of vessels. Details are provided in Table 3.

Primary end-point

The incidence of primary end-point (major/minor bleedings) in the intention-to-treat analysis did not differ between the study arms and occurred in 25.0% vs. 33.3% (p = 0.238). The per-protocol analysis of procedures performed only by independent radial operators (82.4% of cases) showed a significantly higher rate of the primary-end point in the TF arm

Table 2. Baseline clinical characteristics

	Radial access	Femoral access	P
Age [years]	61 (49.7–72.2)	62.8 (50.2–75.4)	0.436
Height [cm]	170.4 (163.2–177.7)	169.2 (159.9–178.5)	0.475
Weight [kg]	76 (60.5–91.5)	77.8 (62.9–92.7)	0.567
Body mass index [kg/m^2]	26 (21.7–30.2)	27 (22.7–31.3)	0.212
Body surface area [m^2]	1.89 (1.659–2.116)	1.89 (1.674–2.104)	0.948
Pulse [bpm]	82 (60.8–103.0)	78 (58.5–97.1)	0.295
Systolic blood pressure [mm Hg]	140.5 (110.2–170.8)	132.2 (107.1–157.3)	0.136
Diastolic blood pressure [mm Hg]	77.5 (59.1–95.9)	70.8 (55.8–85.9)	0.051
Hypertension	69.8%	68.2%	1.00
Diabetes type 2	18.2%	27.7%	0.33
Previous myocardial infarction	7.7%	8.3%	1.00
Hyperlipidaemia	69.2%	75.0%	0.66
Chronic kidney disease	12.0%	18.4%	0.41
Peripheral artery disease	13.2%	15.4%	1.00
Smoking	65.3%	66.7%	1.00
Oral anticoagulation	2.6%	0.0%	0.49
Dysthyroidism	10.0%	12.5%	1.00
Carotid artery stenosis	7.9%	5.1%	0.66
Haemoglobin [g/dL]	13.7 (12.2–15.2)	13.9 (12.5–15.3)	0.446
Platelets [$\times 10^3/\mu$L]	235.1 (169.2–301.0)	226.5 (157.3–295.7)	0.524
Troponin [ng/mL]	6.5 (0.00–18.17)	20.4 (0.00–77.28)	0.089
Creatinine [mg/dL]	1.0 (0.6–1.4)	1.0 (0.6–1.4)	0.457
eGFR [mL/min./1.72 m^2]	86.5 (62.4–110.6)	87.9 (59.7–116.2)	0.794
Total cholesterol [mg/dL]	201 (153.3–248.7)	197.6 (155.7–239.4)	0.71
LDL-cholesterol [mg/dL]	128.4 (89.4–167.4)	121.9 (82.1–161.7)	0.434
HDL-cholesterol [mg/dL]	42.6 (26.7–58.5)	44.4 (30.5–58.3)	0.561
Triglycerides [mg/dL]	169.3 (31.8–306.8)	144.7 (70.1–219.3)	0.28

Values presented as average (95% confidence interval) if not indicated otherwise; eGFR — estimated glomerular filtration rate; LDL — low density lipoprotein; HDL — high density lipoprotein

(17.4% vs. 36.8%, p = 0.038). Patients who did not receive IIb/IIIa inhibitor had lower risk of bleedings (HR = 0.519, 95% CI 0.244–1.106, p = 0.066). We did not observe any differences among other predefined subgroups (Table 4). A simplified meta-analysis, including the results of OCEAN RACE, showed a risk reduction of major bleedings in TR compared to TF (HR 0.48, 95% CI 0.35–0.66, p < 0.01) (Fig. 2).

Secondary end-point

Angiographic success was achieved in 95.1% of patients (TR: 98.1% vs. TF: 92.2%, p = 0.205). In 99% of cases, the operator was able to cross the lesion with a guidewire. The only two cases where crossing was not possible occurred in the TR arm. The clinical efficacy was reached in 79.6% and was numerically better in the TR arm (TR: 84.6% vs. 74.5%, p = 0.152). The incidences of MACE (TR: 9.6% vs. 11.8%, p = 0.48) and death (TR: 2.0% vs. TF: 6.0%, p = 0.31) during the in-hospital stay were equally balanced between both arms and are presented in more detail in Table 5. The average and maximum long-term follow-up was 478 days and 891 days, respectively. Among non-survivors, half died within the first 129 days after PCI. The long-term mortality was 9.8%. Both vascular approaches had a similar risk of mortality, i.e. TR: 7.8% vs. TF: 11.8%, p = 0.741 (Fig. 3).

DISCUSSION

The risk of major and minor bleedings was not statistically different between the TR and TF, however per-protocol analysis showed a strong trend for lower risk of bleeding in the TR arm. This was confirmed in patients treated by experienced operators. These findings support current recommendations for using a radial approach in the STEMI population [1]. The association of major bleedings with increased risk of death has been observed across different cardiac disease populations [7]. The

primary end-point in our study was safety oriented. A similar design was employed by Czech researchers who conducted the STEMI-RADIAL trial [8]. Between 2009 and 2012, they randomised 707 STEMI patients to TR (n = 348) or TF (n = 359) PCI performed by experienced radialists [8]. The study population was similar to that in our study, with an average age of 62 ± 11 years, 77% male, 21% diabetes, 61% hypertension and 51% smoking. The primary end-point, defined as HORIZONS-AMI bleeding or haematoma larger than 15 cm within 30 days, occurred in 1.4% in the TR arm vs. 7.2% in the TF arm (p = 0.0001) and was mainly driven by a reduction in local bleedings (TR: 0.6% vs. TF: 5.3%, p < 0.01) [9]. The second important trial to address the issue of vascular access in STEMI patients was the Radial Versus Femoral Randomised Investigation in ST-Elevation Acute Coronary Syndrome (RIFLE–STEACS) study [10]. This was a truly large randomised trial conducted by Dutch researchers at four cardiology centres that routinely used a radial approach. Patients with ACS with ST segment elevation were included and randomised 1:1 to TR (n = 501) and TF (n = 500) arms. 30 incidents of MACE were assessed; these included cardiovascular death, recurrent myocardial infarction, stroke, repeat revascularisation and non coronary artery bypass grafting (non-CABG) bleedings. At 30 days, risk of MACE was significantly lower in the TR arm (TR: 13.6% vs. TF: 21.0%, p = 0.003). There were less major non-CABG

Table 3. Angiographic findings and angioplasty characteristics

	Radial access	Femoral access	P
Coronary flow:			
TIMI 0	58.9%	66.7%	0.275
TIMI 1	3.9%	8.3%	0.310
TIMI 2	19.6%	14.6%	0.347
TIMI 3	17.6%	10.4%	0.230
Target lesion localisation:			
Left main	1.9%	0.0%	0.510
Left anterior artery	40.4%	52.0%	0.164
Diagonal branch	5.8%	2.0%	0.324
Right coronary artery	44.2%	34.0%	0.196
Circumflex artery	5.7%	6.0%	0.642
Marginal branch	1.9%	6.0%	0.294
Stent implantation	88.6%	87.5%	0.568
Angioplasty characteristics:			
Thrombectomy	54.8%	58.3%	0.465
GP IIb/IIIa inhibitor	59.2%	66.7%	0.296
Stent implantation	13.2%	2.0%	0.038
Number and types of stents:			
1 stent	69.2%	66.7%	0.473
2 stents	17.3%	13.7%	0.410
3 stents	3.8%	3.9%	0.684
Bare metal stent	76.9%	74.5%	0.478
Drug eluting stent	15.4%	9.8%	0.290
Stent length [mm]	22.6 ± 14.84	19.3 ± 11.54	0.211
IVUS during PCI	0.0%	8.3%	0.279

GP IIb/IIIa inhibitor — glycoprotein IIb/IIIa inhibitor; TIMI — Thrombolysis in Myocardial Infarction flow classification; IVUS — intravascular ultrasound; PCI — percutaneous coronary intervention

Table 4. Primary-end point overall and subgroup analysis

	HR (95% CI)	P
Overall	0.822 (0.522–1.224)	0.238
Age < 65 years	0.642 (0.399–1.031)	0.820
Age ≥ 65 years	1.4 (0.599–3.27)	0.336
Women	0.773 (0.242–2.465)	0.493
Men	0.754 (0.365–1.558)	0.306
BMI ≥ 25	0.97 (0.483–1.946)	0.306
BMI < 25	0.536 (0.14–2.051)	0.572
Operators in training	2.083 (0.702–6.186)	0.184
Independent operators	0.519 (0.244–1.106)	0.066
No GP IIb/IIIa inhibitor	0.429 (0.153–1.201)	0.095
GP IIb/IIIa inhibitor	1.034 (0.448–2.388)	0.584
No renal insufficiency	0.629 (0.302–1.311)	0.157
Renal insufficiency	1.125 (0.381–3.324)	0.622

HR — hazard ratio; 95% CI — 95% confidence interval; BMI — body mass index; GP IIb/IIIa inhibitor — glycoprotein IIb/IIIa inhibitor

Table 5. Major adverse cardiac events during in-hospital stay

	Radial access (n = 52)	Femoral access (n = 51)	P
Major adverse cardiac events	9.6% (n = 5)	11.8% (n = 6)	0.48
Stroke	3.9% (n = 2)	2.0% (n = 1)	0.51
Death	2.0% (n = 1)	6.0% (n = 3)	0.31
Sudden cardiac arrest	4.0% (n = 2)	5.9% (n = 3)	0.51
Major bleeding REPLACE-2	5.8% (n = 3)	3.9% (n = 2)	0.51
Repeat revascularisation	0% (n = 0)	0% (n = 0)	–

REPLACE-2 — Randomised Evaluation in Percutaneous Coronary Intervention Linking Angiomax to Reduced Clinical Events 2

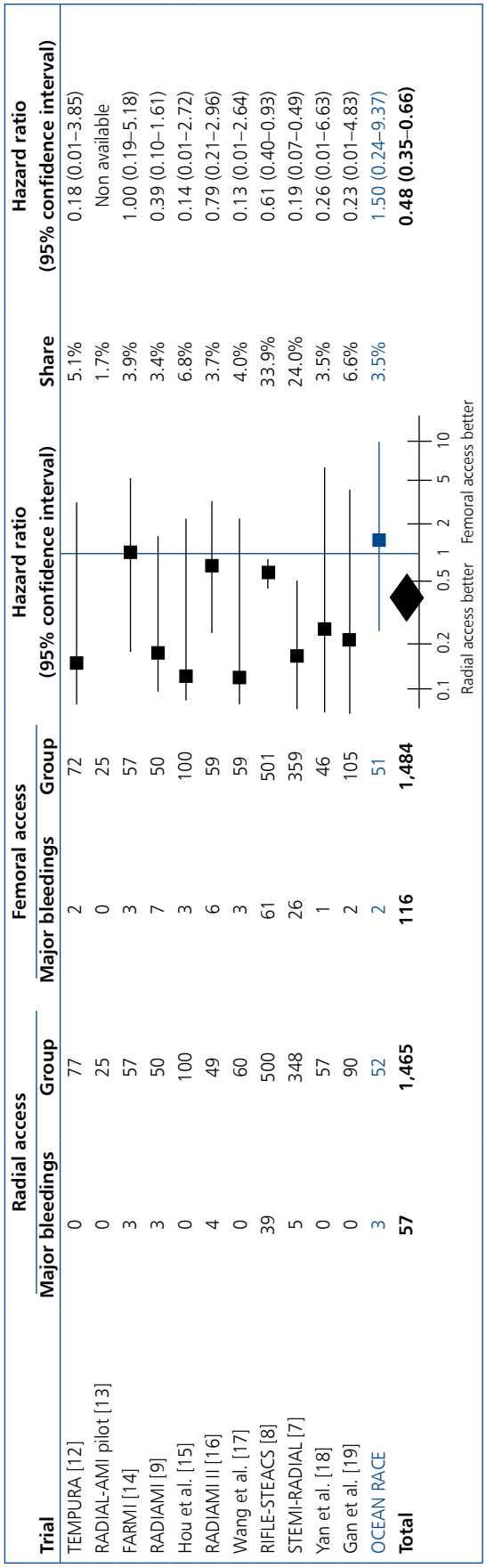

Figure 2. Meta-analysis of randomised controlled trials in ST segment elevation myocardial infarction patients — major bleedings; major bleedings are defined by the TIMI scale, REPLACE-2 scale or as one of the following: bleeding requiring blood transfusion or surgical intervention, fatal bleeding, drop of hemoglobin of > 3 g/dL/haematocrit of > 15%, intracranial bleeding or tapenade

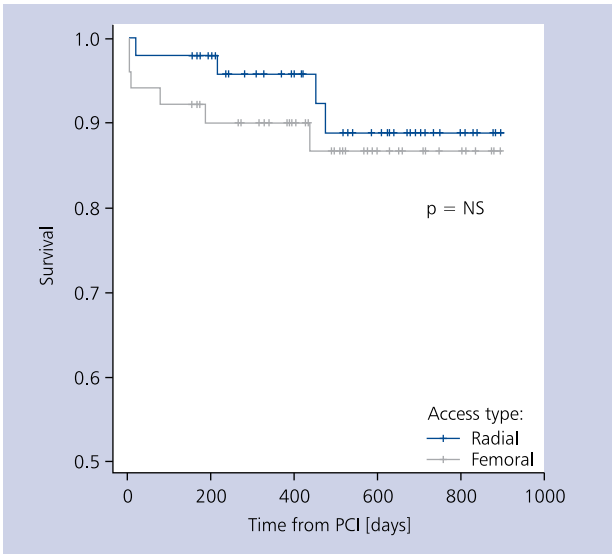

Figure 3. Kaplan-Meier event curves for mortality; PCI — percutaneous coronary intervention; NS — not significant (> 0.05)

bleedings (TR: 7.8% vs. TF: 12.2%, p = 0.026) and less access site related bleedings (TR: 2.6% vs. 6.8%, p = 0.002). One of the first randomised trials that focused on the risk of MACE and angiographic success related to vascular access among STEMI patients was the Polish RADIAMI trial published in 2009 [11]. The authors assessed 100 patients in a randomised manner (TR: n = 50/TF: n = 50). The overall angiographic success was 90% (TR: 88% vs. TF: 92%, p = NS). Comparably to our results, there were no significant differences in terms of MACE risk (TR: 4% vs. TF: 8%, p = NS), major bleedings (TR: 6% vs. TF: 14%, p = 0.18) and local haematomas > 5 cm (TR: 10% vs. TF: 18%, p = 0.37) [11]. To date, 11 randomised clinical trials have compared TR against TF accesses in STEMI patients treated with PCI (Table 6) [12–19]. For the sake of the discussion, and to understand better the overall impact of vascular access selection, we analysed the reported risks of major bleeding and performed a simplified meta-analysis based on recently published reviews by including the results of OCEAN RACE that showed a significant benefit of TR over TF that is consistent with other meta-analyses published so far [20, 21].

CONCLUSIONS

Vascular access remains an important modifiable risk factor in STEMI patients treated with PCI. Although we were not able to show an advantage of TR over TF access in the total population, based on the subanalysis of patients treated by experienced operators, TR over TF seems to be preferred, and translates into a lower risk of MACE. The impact of vascular choice on quality of life and costs is still not clear and requires further analysis.

Conflict of interest: *none declared*

Table 6. List of randomised controlled trials (RCT) assessing radial vs. femoral (TR/TF) vascular access in patients with ST segment elevation myocardial infarction

Acronym or Authors	Year	Study type	Number of patients (TR/TF)	Primary end-point	Follow-up
TEMPURA [12]	2002	RCT, single centre	77/72	MACE	9-month
RADIAL-AMI pilot [13]	2005	RCT, multicentre	25/25	Time to reperfusion, MACE	30-day
FARMI [14]	2007	RCT, multicentre	57/57	Vascular complications, angiographic efficacy	In-hospital
RADIAMI [11]	2009	RCT, single centre	50/50	Not predefined	In-hospital
Gan et al. [19]	2009	RCT, multicentre	90/105	MACE	
Hou et al. [15]	2010	RCT, single centre	100/100	MACE, procedural data	30-day
RADIAMI II [16]	2011	RCT, single centre	49/59	MACE, major bleeding	In-hospital
Wang et al. [17]	2012	RCT, single centre	60/59	Procedural data	In-hospital
RIFLE-STEACS [10]	2012	RCT, multicentre	500/501	MACE	30-day
STEMI-RADIAL [8]	2012	RCT, multicentre	348/359	Major bleedings (HORIZONS-AMI), local haematoma > 15 cm	30-day
Yan et al. [18]	2012	RCT, multicentre	57/46	MACE, procedural data	30-day

MACE — major cardiac adverse event

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Porównanie dostępu promieniowego z dostępem udowym w przezskórnych interwencjach wieńcowych u chorych z zawałem serca z uniesieniem odcinka ST: badanie OCEAN RACE

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Streszczenie

Wstęp: Przezskórne leczenie chorych z zawałem serca z uniesieniem odcinka ST (STEMI) jest postępowaniem zalecanym w wytycznych Europejskiego i Polskiego Towarzystwa Kardiologicznego. Wyboru dotyczącego dostępu naczyniowego dokonuje operator i ma to potencjalnie istotny wpływ na ryzyko powikłań krwotocznych oraz skuteczność zabiegową.

Cel: W celu oceny korzyści ze stosowania dostępu promieniowego przeprowadzono prospektywne, randomizowane badanie kliniczne.

Metody: Chorych przydzielono do grupy leczonej z dostępu od tętnicy promieniowej (TR) lub udowej (TF). Pierwszorzędowym złożonym punktem końcowym było wystąpienie dużego krwawienia ocenianego wg skali REPLACE-2 lub małego krwawienia wg skali EASY (grupa TR) lub skali FEMORAL (grupa TF). Ponadto oceniano skuteczność zabiegową i przeżycie wewnątrzszpitalne oraz odległe.

Wyniki: Analizie poddano 103 chorych, 52 z grupy TR i 51 z grupy TF. Badane populacje nie różniły się pod względem wyjściowej charakterystyki klinicznej i demograficznej. Pierwszorzędowy punkt końcowych wystąpił równie często w obu grupach (TR: 25,0% *vs*. TF: 33,3%; p = 0,238). Wyniki analizy *per protocol* wykazały istotną statystycznie korzyść w grupie TR leczonej przez samodzielnych operatorów (17,4% *vs*. 36,8%; p = 0,038). Duże krwawienia wg skali REPLACE-2 wystąpiły u 4,2% pacjentów (TR: 5,8% *vs*. TF: 3,9%; p = 0,509). Nie stwierdzono istotnych różnic pod względem dużych zdarzeń sercowo-naczyniowych, które zaobserwowano u 10,7% chorych (TR: 9,6% *vs*. TF: 11,8%; p = 0,48). W grupie TF wystąpiły: trend wyższego ryzyka krwawień miejscowych (TR: 22,4% *vs*. TF: 37,7%; p = 0,081) i istotnie większa liczba miejscowych krwiaków w klasie III EASY/FEMORAL (TR: 0% *vs*. TF: 9,8%, p = 0,027).

Wnioski: Nie wykazano znamiennych różnic między dostępem TR i TF pod względem bezpieczeństwa i skuteczności angioplastyki wieńcowej u chorych ze STEMI. Pacjenci leczeni przez samodzielnych operatorów potencjalnie mogą odnieść korzyść z dostępu TR. Potwierdzono wysoką skuteczność i bezpieczeństwo leczenia przezskórnego chorych ze STEMI.

Słowa kluczowe: STEMI, dostęp promieniowy, dostęp udowy, duże krawawienia

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